93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: August 12, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–19879 Filed 8–18–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel, Clinical Trials and Planning Grants.

Date: September 9, 2009.

Time: 10 a.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge 6700, 6700B Rockledge Drive, Bethesda, MD 20817 (Telephone Conference Call).

Contact Person: Brenda Lange-Gustafson, PhD, Scientific Review Officer, NIAID/NIH/DHHS, Scientific Review Program, Room 3122, 6700–B Rockledge Drive, MSC–7616, Bethesda, MD 20892–7616, 301–451–3684, *bgustafson@niaid.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: August 12, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–19877 Filed 8–18–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0664]

Methodologies for Post-Approval Studies of Medical Devices; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop entitled ''Methodologies for Post-Approval Studies of Medical Devices.'' The purpose of the workshop is to facilitate discussion among FDA, industry, academia, professional societies, clinical investigators and other interested parties on issues related to methodologies for post-approval studies of medical devices. The target audiences for this workshop are Epidemiologists, Statisticians, Clinicians and Regulatory Affairs Specialists.

Dates and Times: The workshop will be held on September 9, 2009, from 9 a.m. to 5 p.m. and September 10, 2009, from 9 a.m. to 5 p.m. Participants are encouraged to arrive early to ensure time for parking and security screening before the meeting. Security screening will begin at 8 a.m., and registration will begin at 8:30 a.m. Please pre-register for the workshop by following the instructions in this document.

Location: The workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Silver Spring, MD 20993.

Contact Persons: Daniel Caños, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., WO66/Room 4120, Silver Spring, MD 20993, 240–796–6057, *daniel.canos@fda.hhs.gov* ; or Ellen Pinnow, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., WO66/Room 4106, Silver Spring, MD 20993, 301–796–6066, *ellen.pinnow@fda.hhs.gov*

Registration: To register for the conference please visit the following Web site: *https://medsun2.S-3.net/FDAPASWkshpSep09*. There is no fee to attend the workshop, but attendees must register in advance. The registration process will be handled by Social and Scientific Systems, which has extensive experience in planning, executing, and organizing educational meetings. Although the facility is spacious, registration will be on a first-come, first-served basis. In-person attendance is limited to 120 participants. You may also register to attend the meeting via webcast. Non-U.S. citizens are subject to additional security screening, and they should register as soon as possible. If you need special accommodations because of a disability, please contact Daniel Caños (see *Contact Persons*) at least 7 days before the public workshop.

SUPPLEMENTARY INFORMATION:

I. Why Are We Holding This Public Workshop?

The purpose of the public workshop is to facilitate discussion among FDA and other interested parties on methodological issues related to Post-Approval Studies for medical devices.

II. What Are the Topics We Intend To Address at the Public Workshop?

We hope to discuss a large number of issues at the workshop, including, but not limited to:

- Regulatory requirements for conducting Post-Approval Studies for medical devices;
- Using existing infrastructure (e.g., registries) to facilitate Post-Approval Studies;
- Using innovative study design strategies and advanced epidemiologic methods to enhance and facilitate Post-Approval Studies;
- Review important measurement considerations inherent to Post-Approval Studies;
- Clinical research organizations, industry, academia, and other clinical trial consultant's perspectives on all of the previous issues related to Post-Approval Study methodologies for medical devices.

III. Where Can I Find Out More About This Public Workshop?

Background information on the public workshop, registration information, the agenda, information about lodging, and other relevant information will be posted, as it becomes available, on the Internet at *http://www.fda.gov/cdrh/meetings.html*.

Dated: August 12, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. 09–19904 Filed 8–18–09; 8:45 am]

BILLING CODE 4160–01–S